



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2023-0409; FRL-11232-01-OCSP]

RIN 2070-ZA16

Phenol; Revoking Exemption from the Requirement of a Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to revoke the tolerance exemption for residues of the antimicrobial pesticide ingredient phenol when used as an inert ingredient (solvent/cosolvent) in pesticide formulations applied to growing crops. This rulemaking is proposed on the Agency's own initiative under the Federal Food, Drug, and Cosmetic Act (FFDCA) to implement a tolerance action the Agency determined was appropriate during the registration review conducted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for phenol. EPA is proposing to revoke this tolerance exemption because it corresponds to a use no longer current or registered under FIFRA in the United States.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2023-0409, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/>

dockets.

FOR FURTHER INFORMATION CONTACT: Anita Pease, Antimicrobials Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: 202-566-0736; email address: *pease.anita@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111), *e.g.*, agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), *e.g.*, cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), *e.g.*, agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), *e.g.*, agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any

aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2023-0409, in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2023-0409, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Background

A. What action is the Agency taking?

EPA is proposing to revoke the tolerance exemption in 40 CFR 180.920 for residues of the antimicrobial pesticide ingredient phenol when used as an inert ingredient (solvent/cosolvent) in pesticide formulations applied to growing crops, because this tolerance exemption corresponds to a use no longer current or registered under FIFRA in the United States.

B. What is the Agency's authority for taking this action?

EPA is proposing this action pursuant to its authority under section 408 of the FFDCA, 21 U.S.C. 346a. The Agency previously determined this action was appropriate during the registration review of phenol conducted under FIFRA, 7 U.S.C. 136 *et seq.*

Under FIFRA section 3(g), 7 U.S.C. 136a(g), EPA is required to periodically review all registered pesticides and determine if those pesticides continue to meet the standard for registration under FIFRA. *See also* 40 CFR 155.40(a). As part of registration review, EPA evaluates whether existing tolerances are safe, whether any changes to existing tolerances are necessary or appropriate, and whether any new tolerances are necessary. A “tolerance” represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 346a, authorizes the establishment, modification, and revocation of tolerances or exemptions from the requirement of a tolerance for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Residues of pesticides in or on food that are not covered by a tolerance or exemption are deemed unsafe, 21 U.S.C. 346a(a)(1). Any food containing unsafe residues is considered adulterated and may not be distributed in interstate commerce, 21 U.S.C. 331(a), 342(a)(2)(B). For a food-use pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA but also must be registered under FIFRA, 7 U.S.C. 136 *et seq.* Moreover, residues of food-use pesticides not registered in the United States must also be covered by a tolerance or exemption in order for commodities treated with those pesticides to be imported into the United States.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the

requirement of a tolerance only if EPA determines that the tolerance is “safe.” Section 408(c)(2)(A)(ii) of the FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(c)(2)(B) of the FFDCA requires EPA, when making a safety determination concerning an exemption, to take into account, among other relevant considerations, the considerations listed in section 408(b)(2)(C) and (D). Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....” Section 408(b)(2)(D) identifies various factors, including available information on aggregate and cumulative exposure, for EPA’s consideration in making a safety determination.

Section 408(e) of the FFDCA, 21 U.S.C. 346a(e), authorizes EPA to initiate a rulemaking to establish, modify, or revoke tolerances or exemptions from the requirement of a tolerance on its own initiative. Prior to issuing the final regulation, section 408(e)(2) requires EPA to issue a notice of proposed rulemaking for a 60-day public comment period, unless the Administrator for good cause finds that it would be in the public interest to have a shorter period and states the reasons in the rulemaking.

Consistent with its obligations under FIFRA section 3(g) and FFDCA section 408, EPA has reviewed the available scientific data and other relevant information and determined it is appropriate to take the action being proposed in this rulemaking.

C. When Does This Action Become Effective?

EPA is proposing that this action become effective six months after the date of publication of the final rule in the ***Federal Register***. EPA is proposing this effective date for this action to allow a reasonable interval for producers in exporting members of the World Trade

Organization's (WTO's) Sanitary and Phytosanitary (SPS) Measures Agreement to adapt to the requirements of the final rule.

Any commodities treated with phenol in the channels of trade following the tolerance exemption revocation shall be subject to FFDCA section 408(l)(5), 21 U.S.C. 346a(l)(5). Under this section, any residues of this pesticide in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that the residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA and the residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption, unless EPA determines that consumption of legally treated food during the period of its likely availability in commerce will pose unreasonable dietary risk. Evidence to show that food was lawfully treated may include records that verify the dates when the pesticide was applied to such food.

III. Proposed Rule

EPA is proposing to revoke the tolerance exemption in 40 CFR 180.920 for residues of phenol when used as an inert ingredient (solvent/cosolvent) in pesticide formulations applied to growing crops. In the August 2020 Phenol and Salt Interim Registration Review Decision (available at <https://www.regulations.gov> in docket ID number EPA-HQ-OPP-2012-0810), EPA determined that there are no current registrations for pesticide products containing phenol as an inert ingredient (solvent/cosolvent) for use on growing crops, and therefore the tolerance exemption for phenol under 40 CFR 180.920 is not necessary and should be revoked. Moreover, there have been no registrations for use associated with this tolerance exemption for many years. The Agency therefore believes that existing stocks of pesticide products containing phenol for the use associated with this tolerance exemption have been exhausted and that treated commodities have cleared the channels of trade.

IV. Conclusion

Therefore, EPA is proposing to revoke the exemption from the requirement of a tolerance

for residues of phenol when used as an inert ingredient (solvent/cosolvent) in pesticide products used on growing crops.

V. Statutory and Executive Order Reviews

In this proposed rule, EPA is proposing to revoke a specific tolerance exemption under its authority in FFDCA section 408(e). The Office of Management and Budget (OMB) has exempted this type of action (*e.g.*, tolerance exemption revocation for which extraordinary circumstances do not exist) from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866, due to its lack of significance, this proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*) or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*). Nor does it require any special considerations as required by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This proposed rule does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether revocations of tolerances might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. This analysis was

published in the ***Federal Register*** of December 17, 1997 (62 FR 66020) (FRL-5753-1) and was provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticide named in this proposed rule, the Agency hereby certifies that this proposed rule will not have a significant negative economic impact on a substantial number of small entities. In a memorandum dated May 25, 2001, EPA determined that eight conditions must all be satisfied in order for an import tolerance or tolerance exemption revocation to adversely affect a significant number of small entity importers, and that there is a negligible joint probability of all eight conditions holding simultaneously with respect to any particular revocation. (This Agency document titled “RFA/SBREFA Certification for Import Tolerance Revocation” is available in the docket of this proposed rule.) Furthermore, for the pesticide named in this proposed rule, the Agency knows of no extraordinary circumstances that exist as to the present proposed rule that would change EPA's previous analysis. Any comments about the Agency's determination should be submitted to the EPA along with comments on the proposed rule and will be addressed prior to issuing a final rule.

In addition, the Agency has determined that this proposed rule will not have a substantial direct effect on States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999). Executive Order 13132, requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.” This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This proposed rule does

not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed rule does not have any “tribal implications” as described in Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175, does not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 14, 2023.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL
RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

§180.920 [Amended]

2. In §180.920, amend table 1 by removing the inert ingredient “Phenol”.

[FR Doc. 2023-18050 Filed: 8/21/2023 8:45 am; Publication Date: 8/22/2023]